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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,665	11/21/2003	Zairen Sun	ORIGEN-0009-D01	9053

23599 7590 01/11/2006

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
HADDAD, MAHER M	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/717,665	SUN ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-31 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

1-29. Claims 1-6, drawn to an isolated differentially-regulated human angiogenesis polynucleotide of SEQ ID NO:1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, 49, 51, 53, 55 and 57 **RESPECTIVELY** encoding a polypeptide of SEQ ID NO: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56 and 58 **RESPECTIVELY**, classified in Class 536, subclass 23.5.

30-58. Claims 7-10, drawn to an isolated differentially-regulated human angiogenesis polypeptide of SEQ ID NO: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56 and 58 **RESPECTIVELY**; classified in Class 530, subclasses 395.

59-87. Claims 11-14, drawn to a method of detecting a nucleic acid coding for a differentially-regulated human angiogenesis gene comprising contacting a sample comprising nucleic acid with a polynucleotide probe specific for a differentially-regulated human angiogenesis gene of SEQ ID NO: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, 49, 51, 53, 55 and 57 **RESPECTIVELY**, Wherein said detecting is performed by Northern blot analysis, classified in Class 435, subclass 6.

89-106. Claims 11-14, drawn to a method of detecting a nucleic acid coding for a differentially-regulated human angiogenesis gene comprising contacting a sample comprising nucleic acid with a polynucleotide probe specific for a differentially-regulated human angiogenesis gene of SEQ ID NO: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, 49, 51, 53, 55 and 57 **RESPECTIVELY**, Wherein said detecting is performed by Polymerase chain reaction (PCR), classified in Class 435, subclass 6.

107-135. Claims 11-14, drawn to a method of detecting a nucleic acid coding for a differentially-regulated human angiogenesis gene comprising contacting a sample comprising nucleic acid with a polynucleotide probe specific for a differentially-regulated human angiogenesis gene of SEQ ID NO: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, 49, 51, 53, 55 and 57 **RESPECTIVELY**, Wherein said detecting is performed by reverse transcriptase PCR, classified in Class 435, subclass 6.

136-164. Claims 11-14, drawn to a method of detecting a nucleic acid coding for a differentially-regulated human angiogenesis gene comprising contacting a sample comprising nucleic acid with a polynucleotide probe specific for a differentially-regulated

human angiogenesis gene of SEQ ID NO: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, 49, 51, 53, 55 and 57 **RESPECTIVELY**, Wherein said detecting is performed by RACE PCR, classified in Class 435, subclass 6.

165-193. Claims 11-14, drawn to a method of detecting a nucleic acid coding for a differentially-regulated human angiogenesis gene comprising contacting a sample comprising nucleic acid with a polynucleotide probe specific for a differentially-regulated human angiogenesis gene of SEQ ID NO: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, 49, 51, 53, 55 and 57 **RESPECTIVELY**, Wherein said detecting is performed by *in situ* hybridization, classified in Class 435, subclass 6.

194-222. Claims 15-16, drawn to a method of treating a vascular disease or a disease associated with vascularization comprising administering to a subject an antibody specific for a polypeptide of SEQ ID NO: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56 and 58 **RESPECTIVELY**, classified in Class 424, subclass 130.1.

223-251. Claim 17, drawn to a method for identifying an agent that modulates the expression of a differentially-regulated angiogenesis polynucleotide or polypeptide encoded thereby in cells capable of forming blood vessels, comprising contacting said cells with polypeptide of SEQ ID NO: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56 and 58 **RESPECTIVELY**, classified in Class 435, subclass 7.1.

252-280. Claim 17, drawn to a method for identifying an agent that modulates the expression of a differentially-regulated angiogenesis polynucleotide or polypeptide encoded thereby in cells capable of forming blood vessels, comprising contacting said cells with polynucleotide of SEQ ID NO: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, 49, 51, 53, 55 and 57 **RESPECTIVELY**, classified in Class 435, subclass 6.

281-309. Claims 18-19, drawn to a method of determining the angiogenic index of a sample comprising cells comprising assessing the expression level of polynucleotide of polynucleotide of SEQ ID NO: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, 49, 51, 53, 55 and 57 **RESPECTIVELY,** wherein the angiogenic index is assessed by PCR, classified in Class 435, subclass 6.

310-338. Claims 18 and 20, drawn to a method of determining the angiogenic index of a sample comprising cells comprising assessing the expression level of polynucleotide of polypeptide of SEQ ID NO: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56 and 58 **RESPECTIVELY,** wherein the angiogenic index is assessed using specific antibodies against polypeptide of SEQ ID

NO: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56 and 58 **RESPECTIVELY**, classified in Class 435, subclass 7.1.

339-367. Claims 21-25, drawn to a method of *stimulating* angiogenesis in a patient comprising cells capable of forming blood vessels, comprising administering an antibody specific for a SEQ ID NO: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56 and 58 **RESPECTIVELY,** wherein the patient having cancer, classified in Class 424, subclass 130.1.

368-396. Claims 21-25, drawn to a method of *stimulating* angiogenesis in a patient comprising cells capable of forming blood vessels, comprising administering an antibody specific for a SEQ ID NO: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56 and 58 **RESPECTIVELY,** wherein the patient having coronary disease, classified in Class 424, subclass 130.1.

397-425. Claims 21-25, drawn to a method of *inhibiting* angiogenesis in a patient comprising cells capable of forming blood vessels, comprising administering an antibody specific for a SEQ ID NO: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56 and 58 **RESPECTIVELY,** wherein the patient having cancer, classified in Class 424, subclass 130.1.

426-454. Claims 21-25, drawn to a method of *inhibiting* angiogenesis in a patient comprising cells capable of forming blood vessels, comprising administering an antibody specific for a SEQ ID NO: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56 and 58 **RESPECTIVELY,** wherein the patient having coronary disease, classified in Class 424, subclass 130.1.

455-483. Claims 26-27, drawn to a method of detecting polymorphisms in a differentially-regulated human angiogenesis gene, comprising comparing the structure of genomic nucleic acid with the complete structure of a differentially-regulated human genes of SEQ ID NO: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, 49, 51, 53, 55 and 57 **RESPECTIVELY**, classified in Class 435, subclass 6.

484-512. Claims 26-27, drawn to a method of detecting polymorphisms in a differentially-regulated human angiogenesis gene, comprising comparing the structure of a polypeptide with the complete structure of a differentially-regulated human genes of SEQ ID NO: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56 and 58 **RESPECTIVELY**, classified in Class 435, subclass 7.1.

513-541. Claims 28-29, drawn to a mammal cell whose genome comprises a functional disruption of a differentially-regulated human angiogenesis polynucleotide of SEQ ID NO: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, 49, 51, 53, 55 and 57 **RESPECTIVELY**; or a mammalian homolog thereof, classified in Class 435, subclass 455.

542-570. Claims 28-29, drawn to a non-human, transgenic mammal comprising a mammal cell whose genome comprises a functional disruption of a differentially-regulated human angiogenesis polynucleotide of SEQ ID NO: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, 49, 51, 53, 55 and 57 **RESPECTIVELY**; or a mammalian homolog thereof, classified in Class 800, subclass 8.

571-599. Claim 30, drawn to an antibody which is specific for an epitope that is specific for a polypeptide of SEQ ID NO: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56 and 58 **RESPECTIVELY** , classified in Class 530, subclass 387.1.

600. Claim 31, drawn to a method of advertising a differentially-regulated human angiogenesis or polypeptide for sale, commercial use or licensing comprising displaying in a computer-readable medium SEQ ID NO: 1-58 **RESPECTIVELY**, classified in Class D20, subclass 10.

3. Groups 1-58 and 513-599 are different products. Nucleic acids, polypeptides, antibodies to the polypeptides, mammalian cells and transgenic mammals differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

4. Groups 59-512 and 600 are different methods. A method of detecting, a method of treating, a method of determining, a method of stimulating, a method of inhibiting and a method of advertising differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

5. Groups 1-29/59-193, 252-309, 454-483, 30-58/223-251, 339-454, 484-512 and 571-599/194-222, 310-338 are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of Groups 571-599 can be used for affinity purification, in addition to the methods of treating and determining recited. The polynucleotides of Groups 1-29 can be used in a method of making the polypeptide, in addition to the methods of detecting, treating and identifying recited.

6. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods

of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

Species Election

7. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

A. If anyone of Groups 368-396 and 426-454 is elected, applicant is required to elect a method of stimulating/inhibiting angiogenesis in a patient, where in the patient having (a) coronary artery disease, (b) myocardial ischemia or (c) coronary arteriosclerosis. These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

B. If Group 455-512 is elected, applicant is required to elect a method of detecting polymorphisms in a differentially-regulated human angiogenesis gene, wherein the polymorphism is a nucleotide (a) deletion, (b) substitution, (c) inversion, or (d) transposition. These are species because these alterations produce different structures, sizes, and physiochemical properties.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 36 is generic.

8. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be

obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 6, 2006

Maher Haddad

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600